



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

d10706

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

June 3, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-SWR-WL-09/7

CFN# 1647845
Facility ID# 179333

Brian MinerD
Director
Coulter Imaging LLC
1900 S. Coulter #N
Amarillo, TX 79106

Dear Mr MinerD:

Your facility was inspected on April 20, 1998 by a representative of the State of Texas, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain parts of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

21 CFR900.12(d)(2): The number of masses scored in the phantom image was 1.0 and did not meet the required number. The minimum number required for masses is 3.

21 CFR900.12(d)(2): The number of fibrils scored in the phantom image was 2.0 and did not meet the required number. The minimum number required for fibrils is 4.

The specific deficiencies noted above appeared under the level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality mammography at your facility.

In addition, a level 2 noncompliance was listed on the inspection report provided to you at the close of the inspection. This noncompliance is:

21 CFR900.12(d)(2): Phantom image test results were not recorded for 4 months.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- ▶ **impose civil money penalties** on a facility of up to \$10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.
- ▶ **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.
- ▶ **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

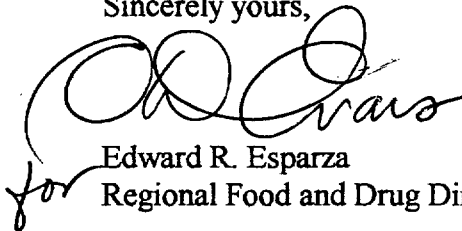
- ▶ the specific steps you have taken to **correct** the violations noted in this letter;
- ▶ each step your facility is taking to **prevent the recurrence** of similar violations;

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Deborah M. McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. McGee at 214-655-8100, extension 138.

Sincerely yours,



for Edward R. Esparza
Regional Food and Drug Director

Page 3

June 3, 1998

cc: Thomas C. Cardwell
X-Ray Branch Administrator
Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091